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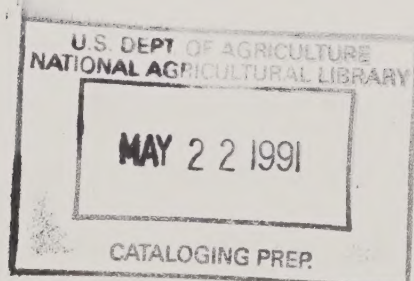
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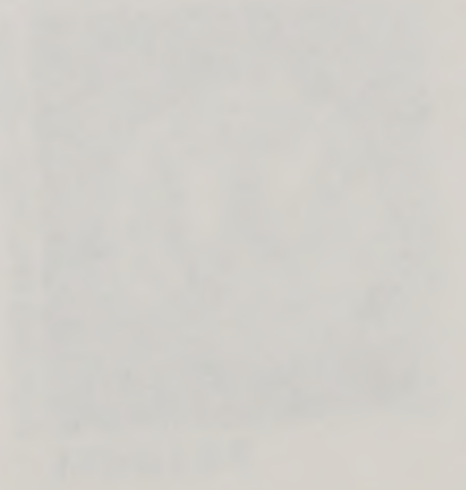
USDA/STATE/EPA ASSESSMENT TEAM OF THE
NATIONAL AGRICULTURAL PESTICIDE IMPACT ASSESSMENT PROGRAM
UNITED STATES DEPARTMENT OF AGRICULTURE

Comments of the Secretary of Agriculture in Response to
the Notice of Intent to Cancel Pesticide Products
Containing Chlordecone, Trade Name Kepone



1. The purpose of this report is to provide a summary of the results of the study conducted by the research team. The study was designed to investigate the effects of the proposed intervention on the target population. The results of the study are presented in the following sections.

2. The study was conducted in a controlled environment. The participants were recruited from a local community and were randomly assigned to the intervention group or the control group. The intervention group received the proposed intervention, while the control group received a placebo. The study was conducted over a period of 12 weeks.



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ACKNOWLEDGMENT

The Assessment Team evaluated the registered uses of chlordecone (Kepone) together with the information which accompanied the Notice of Intent to Cancel Registration of Pesticide Products Containing Chlordecone. The Team consulted with registrants, users and research personnel connected with the various aspects of chlordecone. The team leader, S. N. Fertig and the team members, P. W. Bergman, H. E. Fairchild, and B. R. Wilson contributed to the preparation of this report.

INTRODUCTION

In compliance with provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as Amended, Sections 6(b) and 25, the United States Department of Agriculture has reviewed EPA's Notice of Intent to Cancel Pesticide Products Containing chlordecone (Kepone). The Department has also reviewed the related documents, including, position documents and benefit and risk analyses accompanying the Notice of Intent to Cancel. Even though the Department is concerned by the apparent safety problems associated with the manufacture of chlordecone, the following statements are important to an understanding of the Department's response.

1. The response concerns itself only with the biological efficacy, benefit/risk and exposure aspects of the use of chlordecone as registered.
2. The voluntary cancellation by Allied Chemical Corporation, the sole domestic producer of chlordecone, has not been a factor in determining the Department's response. Under FIFRA, as Amended, our responsibility is in assessing the analysis of the overall impact of regulatory decisions on the ability to effectively control nuisance and damaging pest infestations as they may impinge on the agricultural economy, while preventing any unreasonable adverse effects on man or the environment.

3. The Department recognizes that ants, roaches, and other household pests are not of major concern in agricultural production, but they are significant nuisances and potential health related pests associated with, but not exclusively, farm buildings and farm households. Also, the Department and the Land Grant Colleges and Universities, through research and extension have the scientific expertise to evaluate control measures and have the responsibility for disseminating safe and effective recommendations for control of household pests irrespective of where they may occur. An additional responsibility is the preservation and maintenance of quality of the food supply including compliance with current federal, state, and local health standards.
4. Ants, roaches and other household pests are a major concern in the processing of raw agricultural commodities and in the storage of packaged and processed foods in commerce and in the home.

USE PATTERNS

In the information accompanying the Notice of Intent to Cancel, EPA listed the registered site/pest combinations for chlordecone as follows:

<u>Site</u>	<u>Pest</u>
Commercial - Edible Indoor	American Cockroach, Cockroaches, Southern Fire Ant, Argentine Ant, German Cockroach, Oriental Cockroach, Sweet-Eating Ants, Brownbanded Cockroach, Grease-Eating Ants, Pharaoh Ant, Western Thief Ant

<u>Site</u>	<u>Pest</u>
Commercial - Inedible Indoor	American Cockroach, Cockroaches, German Cockroach, Oriental Cockroach, Silver- fish, Ants, Harvester Ants, Pharaoh Ant, Thief Ant, Brownbanded Cockroach, Crazy Ant, Little Black Ant
Domestic Dwellings - Indoor	American Cockroach, Ants, Argentine Ant, Brownbanded Cockroach, Grease-Eating Ants, Oriental Cockroach, Pyramid Ant Sweet-Eating Ants, Western Thief Ant, California Fire Ant, Crazy Ant, Harvester Ant, Cockroaches, Palmetto Bug, Silver- fish, Thief Ant, German Cockroaches, Little Black Ant, Southern Fire Ant, Waterbugs
Domestic Dwellings - Outdoor	Ants, Cockroaches, Grease-Eating Ants, Millipedes, Silverfish, Waterbugs, Argentine Ant, Crazy Ant, Harvester Ant, Pharaoh Ant, Southern Fire Ant, Western Thief Ant, California Fire Ant, Fire Ant, Little Black Ant, Pillbugs, Sweet-Eating Ants
Flowering Plants	Ants, Cockroaches
Lawns	Ants, Grease-Eating Ants, Sweet-Eating Ants, Cockroaches, Silverfish, Fire Ant, Southern Fire Ant
Ornamental Shrubs	Ants
Ornamental Trees	Ants

The above compilation shows the large number of different pests for which chlordecone is registered and for which this single product will give effective control. Based on current trends in registration/ reregistration, the likelihood of new compounds reaching the market in time to adequately replace this number of registered uses is considered unlikely.

EFFICACY AND BENEFIT

Based on a report "Preliminary Benefit Analysis of Kepone for Control of Ants and Cockroaches in Domestic Dwellings" (August 20, 1976), EPA recognizes and the Department concurs in the following:

1. "Ants and cockroaches are among the most common of household pests. Ants may nest in or under houses or be invaders in search of food. While most ants are simply annoying, some may be dangerous pests due to biting and stinging of humans, and damaging parts of dwellings."
2. "Cockroaches give off an offensive odor and are suspected disease carriers. They prefer damp and warm areas such as under kitchens and bathroom sinks, under refrigerators and cupboards and around pipes and conduits. They feed on a variety of food and refuse including soap, grease, cereals, meats, cheese, and even beer and leather."
3. "Kepone baits and traps are a unique control method. Baits offer a significantly different approach to pest control not found in the use of non-bait alternative controls. Baits attract the pest to the control agent, while non-bait alternatives are directed at the pest. Ants, for example, are attracted to the bait by the sweet or greasy materials mixed with the active ingredient Kepone. Ants feeding on the bait and returning to the nest may carry some of the material with them, thereby exposing additional ants to the bait."

4. "Pest control with baits offer the following advantages:

- No special application equipment is required.
- No special mixing of materials is needed.
- No special care is required to assure that food and utensils are not contaminated as with sprays or dusts. However, certain precautionary recommendations, as with the use of any pesticide, must be followed."

As discussed in the Notice of Intent to Cancel, "...the only alternative to chlordecone bait that is registered in a bait formulation is Baygon. Baygon is registered for use only in a bait against roaches. No alternatives are registered for use in a bait formulation against ants and other household pests. However, many alternatives to Kepone baits are registered in spray and dust formulations for control of roaches, ants, and other household pests."

Use experience has demonstrated that many species of ants and roaches are more effectively controlled by using baits as either a supplement to other insecticides or as the sole formulation.

Of the pesticides listed by EPA as alternatives for ant and roach control, lindane, carbaryl, rotenone and toxaphene are potential candidates for RPAR's. Available EPA listings of restricted use classification for pesticides indicate that some or all uses of lindane, fenthion, chlorophyrifos, HCN, chloropicrin, and methyl bromide may be included. Should these pending actions result in the loss of use through cancellation or lack of availability to the general public by restricted use, the impact on effective control measures could be significant on the ability of homeowners to control their own pests.

Continued regulatory action against registered and effective pesticides for ant and roach control can have an adverse impact.

The Department concurs with EPA's analysis on dollar costs to consumers of chlordecone vs. other pesticides when analyzed on the basis of formulations presently available. We do not believe it is meaningful, to compare chlordecone baits with liquid, dust, or wettable powder formulations of other pesticides unless bait formulations of the others have been prepared and evaluated under use conditions.

The use of insecticides for controlling household pests must be classified in the "minor use" category. Based on current trends in registration/reregistration, the costs involved in generating data for new registrations, and the uncertainty of market potential and protection, it is unlikely that new compounds will reach the market unless they also have efficacy on a major commodity. Where efficacy has been demonstrated and use patterns are such as to pose minimal health and environmental risks as in the case of chlordecone, every effort should be made to retain such uses. Looking to the future, this must be a consideration in planning pest control strategies both for USDA and EPA.

In summary, the Department wishes to emphasize that when used according to label directions, chlordecone as formulated is effective for the control of ants, roaches, and other household pests. Established use experience shows that when inaccessible containers or inaccessible placement are used, the bait displays a high degree of safety in handling with low potential for exposure to humans and animals. Considering the

methods of use and the low concentration of active ingredient involved, the probability of unreasonable adverse effects on the environment is remote. The fact that other pesticides may be available for controlling household pests, does not ameliorate the concern that many of these are (a) currently listed as possible RPAR candidates, (b) designated for restricted use, (c) may exhibit less convenience, (d) could offer greater exposure to humans and animals, and (e) may be less effective. It is important and should be recognized that resistance to chemicals does occur in biological systems. Thus, there is sound justification for maintaining an array of safe pesticides which are properly labeled and when used as directed on the label do not present an unreasonable adverse effect on the environment, including humans.

HEALTH AND ENVIRONMENTAL CONSIDERATIONS

The impact on human health from the continued use of chlordecone for ant and cockroach control was considered by EPA (October 5, 1976) when it prepared the notice of intent to cancel. The Department concurs with the EPA determinations that:

1. The use of chlordecone baits for control of ants and cockroaches is expected to result in minimal human exposure because most traps contain only 0.125 percent active ingredient.
2. The inaccessible traps or products, defined as all enclosed traps made from metal or plastic, as well as metal stakes hammered into the ground, offer very little human risk.

Assessment of risk indicates a low probability of even one case of cancer resulting from the registered uses of 0.125 percent chlordane bait.

3. Some of the inaccessible metal traps are filled with automatic machinery and permanently sealed. While they provide small openings for the ants, they are virtually impossible to open any further without a screw driver or pliers.
4. If chlordane is used in baits according to the label for a three year period, there is no significant risk of cancer from either enclosed traps or accessible baits by the inhalation route.
5. The Pesticide Episode Response Branch, Operations Division, Office of Pesticide Programs, EPA summarized 56 reports involving humans and chlordane. "Of the 56 reports involving humans, 52 involved children under five years of age, two involved adults (17-65) and two specified no age. Of the 52 episodes involving children under five, 43 occurred in the home. Nine did not indicate a location. All home related episodes involved products designed to control household insect pests, primarily ants and roaches. The majority of these involved children who found the pesticide and placed it in their mouths. No symptoms were listed in any of these instances. Several reports stated that treatment rendered was precautionary rather than in response to symptoms."

"Of the two episodes involving adults, one was an attempted suicide and the other a job-related incident in which a man

who worked in a packaging plant developed dermatitis on his hands. No fatalities were reported involving the active ingredient Kepone. The only health effect noted in any of the reports was the dermatitis which occurred as stated above."

6. "The human risk of exposure by inhalation of Kepone from inaccessible products is judged to be low. The dermal and oral exposure of children is also judged to be low."

In summary, the Department believes that the registered use of chlordecone baits for controlling ants, cockroaches and other household pests presents minimal human exposure and hazard because:

1. The baits contain only 0.125 percent active ingredient.
2. There is minimal accessibility to baits in the traps, especially those traps defined as inaccessible by EPA.
3. When chlordecone baits are used according to the label for a three year period, there is no significant risk of cancer via the inhalation route, as concluded by EPA.
4. In the Episode Reports involving humans, there were no indication of poisoning from exposure to chlordecone in any of the reported cases of suspected exposure.

SUMMARY

The Department concurs with the determination of the Administrator of EPA that "distribution, sale, and use of existing stocks of the listed inaccessible chlordecone products are not inconsistent with the purposes of FIFRA as amended and will not have unreasonable adverse effects on the environment." As a matter of record, however,

the Department's assessment is that the combination of inaccessible packaging, the low concentration of active ingredient, the lack of evidence of adverse health effects due to exposure, and the lack of evidence to support adverse environmental contamination lends strong justification for not placing a time period on the availability and use of chlordecone for ant, roach and other household pest control.

Important considerations in the use of pesticides in public buildings and the home are the safety associated with use, the accuracy of application and potential exposure. The use of prepackaged pesticides with pre-measured quantities of active ingredient offer accuracy of application, minimize the likelihood of misuse and exposure in handling and provide distinct advantages of safety to humans and pets. The information prepared by EPA, which accompanied the Notice of Intent to Cancel, supports these favorable characteristics for chlordecone.

In assessing benefit, the dollar cost to consumers is only one aspect of evaluation; whether placed in monetary terms or not, consideration must be given to effectiveness of control, safety in handling, ease of application, level of exposure, safety to humans and animals and potential for environmental contamination.

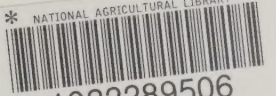
After considering needs in pest control, methods of use, the present and future anticipated registration status of other pesticides, the health and environmental data and the scientific conclusions accompanying the Notice of Intent to Cancel, the Department must conclude that the benefits do exceed the risks for the use of inaccessible bait formulations of chlordecone.

Regarding the baits packaged in an accessible form, the added potential for exposure to children and pets is recognized. The likelihood of children ingesting unenclosed sweetened baits, both stored and as applied, is presumed to be greater than the enclosed baits and may be sufficient to warrant permitting continued use only under restrictive labeling as to placement (inside walls and under stationary appliances) and use only by certified applicators. Use information verifies that for the control of inaccessible colonies of ants and for the control of certain cockroach species, accessible formulations are most effective. Labeling changes to assure inaccessible placement and use only by certified applicators should be considered.

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- EPA. Preliminary Benefit Analysis of Kepone for Control of Ants and Cockroaches in Domestic Dwellings. Prepared by Roger C. Holtorf. August 20, 1976.
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